DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED

September 23, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 66

Joseph J. Pietrafitta
CEO
Laser Peripherals, Inc.
5484 Feltl Road
Minnetonka, Minnesota 55343

Dear Mr. Pietrafitta:

During a recent inspection of your firm located in Minnetonka, MN, the Central Region's Electro-optical Specialist (EOS) determined that your firm manufactures a model LS905 laser fiber adaptor. These adaptors are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The devices are adulterated under Section 501(f)(1)(B) of the Act in that they are Class III devices under Section 513(f) and do not have approved applications for pre-market approval in effect pursuant to Section 515(a) or approved applications for an investigational device exemption under Section 520(g).

The devices are also misbranded under Section 502(o) of the Act in that notices or other information respecting the devices was not provided to FDA by your firm as required by Section 510(k), and the devices were not found to be substantially equivalent to predicate devices.

Additionally, our EOS found these products to be adulterated within the meaning of Section 501(h) in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage or installation are not in conformance with the Good Manufacturing Procedures (GMPs) for Medical Devices as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to create/maintain a device history record that demonstrates the adaptor was manufactured according to the Device Master Record/specifications.

2. The quality assurance records associated with the LS905 adaptor fail to document that all products are tested.

This letter is not intended to be an all-inclusive list of the violations of the Act at your facility. It is your responsibility to insure adherence to each requirement of the Act and its regulations. The violations noted in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject device have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the Food and Drug Administration without further notice. These actions include but are not limited to seizure, injunction and/or civil money penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an

explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure that similar violations do not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response may be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TPN/ccl